UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DATE: October 17, 2006

SUBJECT: Secondary Review of Contractor's (DynCorp Systems & Solutions LLC) Efficacy Review for Pool Frog Mineral Reservoir,
EPA Reg. No. 53735-11;
DP Barcode: D331972

FROM: Lorilyn M. Montford LM 10/17/06
Efficacy Evaluation Team
Antimicrobial Division (7510P)

THRU: Dr. Tajah Blackburn, Ph.D., Acting Team Leader
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APPLICANT: King Technology, Inc.
530 11th Ave. South
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Formulation From Label:

Active Ingredient(s)	% by wt.
Sodium Chloride	0.5%
Inert Ingredient(s)	99.5%
Total	100.0%

I BACKGROUND

The product, Pool Frog Mineral Reservoir (EPA Reg. No. 53735-11), is an EPA-approved swimming pool disinfectant/sanitizer for use in residential swimming pools. The product must be used in conjunction with an EPA-registered source of chlorine (such as Chlorine Bac Pac). The product/chlorine system may also be supplemented with the Frog BAM Algae Preventative (sold separately) to protect against algae. The applicant requested to amend the registration of this product to include use of the product as a spa disinfectant (i.e., Pool Frog Mineral Reservoir [Spa Cartridge] and Pool Frog Mineral Reservoir [Filter Spa Product]). The studies were conducted by Pace Analytical Services, Inc., located at 1700 Elm Street, Suite 200, in Minneapolis, MN 55414.

This data package contained a letter from the applicant's representative to the Agency (dated June 12, 2006), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-35 (Data Matrix), two studies (MRID Nos. 468869-01 and 468869-02), Statements of No Data Confidentiality Claims for both studies, and the proposed label.

II USE DIRECTIONS

The product is designed for disinfecting swimming pools and spas. Directions on the proposed label provided the following information regarding preparation and use of the product as a spa disinfectant: For use in spas up to 600 gallons. Ensure all spa equipment is working properly. The pump and filter should be operated at least 3 hours per day. Clean filter following manufacturer's directions. Adjust pH to between 7.2-7.8. After filling the spa with water, establish a bromine (or chlorine) residual of 1.0-2.0 ppm. Always maintain a bromine (or chlorine) residual of at least 1.0 ppm. Shock spa once a week or as needed. For in-line systems, insert the mineral cartridge into the area marked "Minerals" of the opened In-Line System. For floating systems, push the mineral cartridge into the bottom opening of the floating Spa Frog system. Replace the mineral cartridge after 4 months or when draining and refilling the spa with fresh water.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Waters in Swimming Pools, Spas, Hot Tubs, Whirlpools, and Jacuzzis

Swimming pool (and spa) water disinfection presents a unique combination of variables, including the number of swimmers/bathers, the frequency of use, the frequency with which the water is changed, general environmental conditions, and the type/degree of organic contamination of the water by the swimmers/bathers (e.g., suntan lotions and oils) and by various debris. As a result, both laboratory testing and confirmatory field testing are required.

The effectiveness of swimming pool and spa additives may be substantiated with data derived from the AOAC Disinfectants (Water) for Swimming Pools Method against both

Escherichia coli (ATCC 11229) and *Enterococcus faecium* (ATCC 6569). The method may be modified, such as for pH. An initial bacterial suspension count of 2×10^8 is desired. Time zero bacterial concentrations must be in the range of 9.9×10^5 to 1.5×10^6. Available chlorine at zero time in the NaOCl test control must be within ≥ 0.58 and ≤ 0.62. Results in the NaOCl control test must show complete kill of *Escherichia coli* within 0.5 minutes and *Enterococcus faecium* within 2 minutes. Test results must show the absence of colony growth on dilution plates and the absence of growth in all 5 lactose or thioglycolate tubes to demonstrate complete kill of the test organisms. Product test results must be equivalent to those of the NaOCl control. These Agency standards are presented in DIS/TSS-12 and the AOAC test method itself.

Confirmatory field testing must take place in at least two swimming pools (or spas), under an Experimental Use Permit, lasting for an entire swimming season (4 to 12 months). Reports must include at least the following data regarding the test pools:

(i) The design of the pool, the recirculation and filter systems, and the water capacity

(ii) The daily bather load

(iii) The amount and identification of all chemicals added daily (specifying time, site and method)

(iv) The range of chemical characteristics of the water, such as pH, nitrogenous substances, metals, and hardness

(v) The physical characteristics of the water, including temperature and clarity, determined at least daily

(vi) Daily meteorological data, including air temperature, rainfall, and number of hours of sunlight for outdoor pools

(vii) Bacteriological monitoring should be conducted daily, in accordance with the suggested Ordinance and Regulations Covering Public Swimming Pools of the American Public Health Association. Water samples for bacteriological analysis should be taken on opposite sides of the pool in the shallow area and as remote as possible from the inlets, preferably at the midpoints between inlets. A minimum of 144 samples should be taken during the test period. Samples should be taken just below the surface of the water, and preferably at such times when the number of persons using the pool during the preceding hour has been at least 50% of the maximum bather load of the pool, and the number of persons in the pool water at the time the samples are collected is at least equal to 25% of the maximum bather load of the pool. Pertinent chemical characteristics of the pool water at the sampling site should be determined at the time of sampling.

(viii) The concentration of the antimicrobial agent in the water monitored daily at the same time-intervals that the bacteriological assay samples are obtained

(ix) The method that the product user will employ for monitoring the level (ppm) of antimicrobial agent in the water.

Field test results must show that 85% of the samples collected meet the following indices (i.e., or that not more than 15% of the samples collected fail the following indices): (1) The standard plate count at 35EC shall not exceed 200 colonies/1.0 mL; (2) The most probable number of coliform bacteria shall be less than 2.2 organisms/100.0 mL. When the membrane filter test is used, there shall be no more than 1.0 coliform organisms/50 mL; and (3) The most probable number of enterococcal organisms shall be less than 2.2 organisms/100.0 mL. When the membrane filter test is used, there shall be no more than 1.0 enterococcal organisms/50 mL. These Agency standards are presented in DIS/TSS-12.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 468869-01 "Presumptive Test: Efficacy of Hypobromous Acid Used with Silver Ions as a Spa Disinfectant System," by John Hill and Nicole Weulander. Study conducted at Pace Analytical Services. Study completion date – July 7, 2006. Study Number: KT-0501.

This study was conducted against *Escherichia coli* (ATCC 11229) and *Enterococcus faecium* (ATCC 6569). Testing conformed to the AOAC Disinfectants (Water) for Swimming Pools Method, Method 965.13, as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. A test solution was prepared containing active bromine and a low level of silver ions to reflect the proposed use of 1-Bromo-3-chloro-5,5-dimethylhydantoin (BCDMH) with a source of silver ions. The test solution contained a nominal concentration of 1.3 ppm BCDMH and a nominal concentration of 2.6 ppb silver ions. A 0.62 ppm sodium hypochlorite solution was used as a positive control. The composition of each test solution was determined chemically prior to inoculation. Oxidant concentrations (active chlorine or active bromine) were determined at the end of the test period as well. Suspensions of each challenge microorganism were prepared, with inoculum levels at $2x10^8$ CFU/mL. During use, each culture was adjusted to ~$1x10^6$ CFU/mL. Aliquots (1.0 mL each) of the bacterial suspensions were inoculated into 199 mL of the test or control solutions. Aliquots (1.0 mL each) were removed from the inoculated test solution at time intervals of 30 seconds, 1, 2, 3, 4, 5, and 10 minutes. Each aliquot was immediately transferred to a 9.0 mL neutralizer blank. Serial dilution plate counts were prepared from each neutralizer blank. Aliquots (0.1 mL each) from the 10^{-1} and 10^{-2} dilutions were spread onto tryptone glucose extract agar for *Escherichia coli* and onto trypticase soy agar for *Enterococcus faecium*. Five portions (1.0 mL each) from each neutralizer were transferred to five lactose broth tubes for *Escherichia coli* and five fluid thioglycolate tubes for *Enterococcus faecium*. The subcultures were incubated for 48 hours at 37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. The lactose broth tubes were subcultured to Eosin Methylene Blue Agar for an additional 48 hours for further confirmation of *Escherichia coli* survivors. The fluid thioglycolate tubes were subcultured to S-F Medium for an additional 48 hours for further confirmation of *Enterococcus faecium* survivors.

2. MRID 468869-02 "*Spa Frog* – 2004 Field In-Use Test (Amended Report)," by John E. Hill, David J. Brookman, and Nicole A Weulander. Study conducted by Pace Analytical Services, Inc. Study completion date – March 28, 2006. Amended report date – June 21, 2006. Laboratory Project Identification Number KT-0401.

This study documented a field test run for 4 months (i.e., February 9 through June 8) under the provisions of an Experimental Use Permit, EUP No. 53735-EUP-2. The field test was conducted using two spas. Spa #1 was a 300-gallon spa, with a water depth of approximately 25 inches without bathers. Spa #1 was equipped with 35 jets and two filter cartridges. Two bathers used Spa #1. Spa #2 was a 550-gallon spa, with a water depth of approximately 27 inches without bathers. Spa #2 was equipped with 43 jets and two filter cartridges. Four bathers used

Spa #2. Spa water (in both spas) was maintained between 100-104°F and was circulated at least 2 hours daily. While bathers were in the spa, bromine levels were maintained between 0.9 and 2.25 ppm. Air temperatures in the testing facility were maintained at 70-75°F. Average air temperatures at the spas ranged from 62-79°F, with an overall mean of 69.6°F. The average pH for Spa #1 and Spa #2 was 7.58 and 7.39, respectively, which are within the ideal pH range of 7.20-7.60.

One lot (Lot No. 7-22906-03821-4) of the product, Spa Frog Mineral Cartridge, was used during the field test. Test spas were filled with fresh water 1 week prior to study initiation. The spa water was balanced by the addition of sodium bisulfate to reduce the pH to 7.2-7.8. The product was installed in each spa by allowing it to free float at the water surface, according to label directions. Active bromine was added to the spas throughout the study so that the level of active bromine could be maintained close to design. Potassium monopersulfate was used as a non-chlorine shock treatment after daily bather use. Sodium dichloro-s-triazinetrione was also used as a shock treatment. Water samples were collected approximately 6 inches below the spa water surface. The sample collection points alternated between opposite sides of the spas. Sterile 120 mL coliform water sample containers were used for microbiological samples. Samples for silver, iron, and copper analyses were preserved with nitric acid. All analyses were performed as soon as possible.

The following parameters were tested daily (i.e., at least five times per week): bromine (by Hach Spectrophotometric DPD method), silver ions (by EPA Method 200.8), pH (by EPA Method 150.1), air temperature, water temperature, clarity/turbidity (by EPA Method 180.1 using a Hach 2100P Turbidimeter), bather load, heterotrophic bacteria (by Standard Methods 9215D), *Enterococcus* species (by Standard Methods 9230C), and fecal coliform bacteria (*Escherichia coli*) (by Standard Methods 9222D). The following parameters were tested monthly: iron (by EPA Method 200.8), copper (by EPA Method 200.8), alkalinity (by EPA Method 310.1), nitrogen ammonia (by EPA Method 350.1), calcium hardness (by Standard Methods 2340B), and bromide (by EPA Method 300.0).

V RESULTS

MRID Number	Organism	Time (minutes)	BCDMH and Silver Test Solution		
			CFU/mL Recovered	Lactose Broth Tubes	Eosin Methylene Blue Agar
468869-01	*Escherichia coli*	0.5	<100	No growth	No growth
		1	<100	No growth	No growth
		2	<100	No growth	No growth
		3	<100	No growth	No growth
		4	<100	No growth	No growth
		5	<100	No growth	No growth
		10	<100	No growth	No growth
468869-01	*Enterococcus faecium*	0.5	<100	1/5	1/5
		1	<100	1/5	1/5
		2	<100	No growth	No growth
		3	<100	No growth	No growth
		4	<100	No growth	No growth
		5	<100	No growth	No growth
		10	<100	No growth	No growth

MRID Number	Organism	Time (minutes)	Sodium Hypochlorite Solution		
			CFU/mL Recovered	Lactose Broth Tubes	Eosin Methylene Blue Agar
468869-01	*Escherichia coli*	0.5	<100	No growth	No growth
		1	<100	No growth	No growth
		2	<100	No growth	No growth
		3	<100	No growth	No growth
		4	<100	No growth	No growth
		5	<100	No growth	No growth
		10	<100	No growth	No growth
468869-01	*Enterococcus faecium*	0.5	<100	No growth	No growth
		1	<100	No growth	No growth
		2	<100	No growth	No growth
		3	<100	No growth	No growth
		4	<100	No growth	No growth
		5	<100	No growth	No growth
		10	<100	No growth	No growth

MRID Number	Parameter	As Reported by the Laboratory	
		Spa #1	Spa #2
468869-02	Number of water samples examined	160	160
	Number of water samples exceeding DIS/TSS-12 limits	1	2
	Percentage exceeding DIS/TSS-12 limits	0.63%	1.25%
	DIS/TSS-12 Criterion	#15%	#15%

VI CONCLUSIONS

1. The submitted efficacy data (MRID No. 468869-01) support the use of the product, Spa Frog Mineral Cartridge, as a spa disinfectant when used in conjunction with active bromine within a concentration range of 0.9 and 2.25 ppm. Time zero bacterial concentrations were in the range of 9.9×10^5 to 1.5×10^6. Available chlorine at zero time in the sodium hypochlorite control was within ≥ 0.58 and ≤ 0.62. Control results showed complete kill of both organisms within 0.5 minutes. No growth was observed on dilution plates or in each of the lactose or thioglycolate tubes at the 2-minute interval. Results for the product were equivalent to results for the sodium hypochlorite control, at the 2-minute time interval.

2.The submitted field test data (MRID No. 468869-02) support the use of the product, Spa Frog Mineral Cartridge, as a spa disinfectant when used in conjunction with active bromine within a concentration range of 0.9 and 2.25 ppm. Field test results showed that the standard plate count exceeded 200 colonies/1.0 mL in <15% of the samples collected. The most probable number of coliform bacteria in all samples was no more than 1.0 coliform organisms/50 mL. The most probable number of enterococcal organisms was no more than 1.0 enterococcal organisms/50 mL.

VII RECOMMENDATIONS

1.The submitted efficacy data (MRID No.'s 468869-01 and 468869-02) support the use of the product, Spa Frog Mineral Cartridge, as an effective disinfectant. In the proposed label language the applicant has referred to this product as a "sanitizer". Since "disinfection" claims are more stringent than "sanitizer" claims, it is recommended that the applicant use the word "disinfectant" rather than "sanitizer" on the label.

2. The proposed label claims that the products, Pool Frog Mineral Reservoir [Spa Cartridge] and Pool Frog Mineral Reservoir [Filter Spa Product], effectively destroy bacteria in spas when bromine levels are maintained at 1.0 ppm. Presumptive and field test data provided by the

applicant support this claim.

3. The proposed label claims that the products, Pool Frog Mineral Reservoir [Spa Cartridge] and Pool Frog Mineral Reservoir [Filter Spa Product], effectively destroy bacteria in spas when chlorine levels are maintained at 1.0 ppm. The data package did not include efficacy data to support this new claim. The letter from the applicant's representative to the Agency (dated June 12, 2006), indicates that previously submitted efficacy data support this claim.

4. The proposed label claims that the product, Pool Frog Mineral Reservoir [Filter Spa Product], effectively destroys bacteria in spas when ozone is used. The data package did not include efficacy data to support this new claim. All references to ozone must be removed from the Master Label.